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EXAMINER

HARMON, CHRISTOPHER R

ART UNIT PAPER NUMBER

3721

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/087,563

Applicant(s)

SICCARDI, ALBERTO

Examiner

Christopher R Harmon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-50 is/are pending in the application.
- 4a) Of the above claim(s) 39-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "by directing a gas from a gas applicator toward and across a surface of the film and flowing particles removed from the surface and the gas out through a nozzle juxtaposed the gas applicator such that the film is not touched" (claims 16 and 34, lines 5-7) is not clear. The gas applicator juxtaposed a nozzle would indicate that the nozzle is a separate element not part of the gas applicator. Furthermore, "and flowing particles removed from the surface" is confusing and should possibly moved to the end of the limitation ie. "in order to remove particles from the flowing surface" (if applicant's intended meaning is the same).

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claims 16-17, 24, 27, 30-32, 34, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Koder a (US 4,396,582).

Baldini et al. teach a method for the manufacture and fillings of flexible sterilizable bags comprising printing 2, cleaning 3, and sterilizing of a film 4; aligns the film 4d; welding the film to form a bag 5; welding a valve to the film bag 5b; dosing the bag DOS; filling the bag STO; (figure 2).

In operation, the system forms, sterilizes, fills, and seals printed flexible bags with valves attached. Because the applicant is one of the common inventors of US Patent 4,656,813, the invention and its operation are not discussed here, rather only the improvements upon the invention as understood by the examiner. Baldini et al. do not describe certain limitations claimed by the applicant as improvements upon the commonly owned invention; such as dry cleaning the printed film, humidifying the valve cavity, or using control algorithms for shaping and welding the bags.

Koder a teaches a dry cleaning procedure of a packaging film with purified/filtered air; see figure 5, pump 84. It would have been obvious to one of ordinary skill in the art at the time of the invention to include the dry cleaning procedure as taught by Koder a in the invention of Baldini et al. in order to free the packaging film of foreign substances.

4. Claims 18-20, 28-29, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Koder a as applied to claims

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16-17, 24, 27, 30-32, 34, and 36-37 above, and further in view of Duffey et al. (US 5,129,212).

The modified invention of Baldini et al. does not indicate sterilizing the spouts prior to application to the flexible bag material. Duffey et al. teach a method and apparatus for automatically filling and sterilizing containers in which spouts S are moved along tunnel 122 and sterilized by hydrogen peroxide gaseous medium (column 10, line 7 - column 11, line 33; figures 10-14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to sterilize the spouts prior to applying them to the bag material as taught by Duffey et al. in the modified invention of Baldini et al. in order to maintain a sterile environment throughout the bag manufacturing procedure.

The modified invention of Baldini et al. does not indicate a contribution regulation valve, a constant pressure valve, and a flowmeter. It would have been obvious to one of ordinary skill in the art to include a constant pressure valve for adjusting/regulating the pressure of the system as is well known in the art.

Duffey et al. teach a volume flow meter (not shown) and contribution regulation valve (single head filler valve) 186 operating in a pressurized system (column 13, lines 1-12). A predetermined amount of filling liquid is supplied to the bags accurately.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the flowmeter and valve as taught by Duffey et al. in the modified invention of Baldini et al. to accurately fill the bags.

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5. Claims 21-22, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Koder, and Duffey et al. as applied to claims 18-20, 28-29, and 35 above and further in view of Madsen (US 3,451,403).

The modified invention of Baldini et al., in both instances above, does not disclose detecting electric conductability of the sanitizing solution. Madsen teaches a method and apparatus for determining the purity of a flowing solution or mixture in which "A stream of the solution or mixture is fed into a container after which a diluting or concentrating agent is fed into the container, and measuring means continuously measures the conductivity of the contents of the container." (abstract of the disclosure, lines 3-7). Automatic control means are provided "to switch the feed back to the solution or mixture when the conductivity has declined to a predetermined value..." (abstract of the disclosure, lines 10-12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include a system as described by Madsen in either modified invention of Baldini et al. in order to monitor and control the amount of solution being administered to each bag.

6. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. in view of Koder, as applied to claims 16-17, 24, 27, 30-32, 34, and 36-37 above, and further in view of Ogata (GB 2142282 A).

The modified invention of Baldini et al. does not disclose a "heated" printing procedure. Ogata (GB 2142282 A) teaches an automatic packing machine in which "a heated type is pressed against the receiving roll through the packing sheet and printing

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tape and packing sheet to apply printing to the packing sheet" (claim 1, lines 6-9). It would have been obvious to one of ordinary skill in the art to include the heated printing procedure in the modified invention of Baldini et al. in order to apply printing to the bag material.

7. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. in view of Kadera as applied to claims 16-17, 24, 27, 30-32, 34, and 36-37 above, and further in view of Brennan et al. (US 4,587,793).

Regarding the limitation of a suspension ring, modified Baldini et al. do not provide for this feature. Brennan et al. (US 4,587,793) teach a bag with a suspension aperture 178 (figure 7) providing for hanging of the bag during the infusion process (column 8, lines 53-54). It would have been obvious to one of ordinary skill in the art, at the time of the invention, to include the suspension aperture as taught by Brennan et al. in the modified invention of Baldini et al. in order to support the bag during the infusion process.

8. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldini et al. (US 4,656,813) in view of Kadera as applied to claims 16-17, 24, 27, 30-32, 34, and 36-37 above, and further in view of Aindow et al. (US 5,934,043).

The modified invention of Baldini et al. provides a ultrasonic welder 21 but does not disclose specifically a piezoelectric transducer, sonotrode, etc. as in claim 45. Aindow et al. teach a web cutting apparatus comprising a ultrasonically vibrated anvil 12

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(sonotrode); position transducers 40; and piezoelectric core 142 (figures 5 and 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the various welding elements as taught by Aindow et al. in the modified invention of Baldini et al. in order to seal the web.

### ***Response to Arguments***

9. Applicant's arguments filed 3/18/04 have been fully considered but they are not persuasive. Koderer teaches dry cleaning of the film by air pump 84 connected to air nozzles 82.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R Harmon whose telephone number is 703-308-8643. The examiner can normally be reached on Monday-Thursday from 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 703-308-2187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**EUGENE KIM**  
**PRIMARY EXAMINER**